

REMARKS

I. Introduction

The undersigned thanks Examiner Sweet for his review and consideration of the present Application, including for the time spent discussing the art and potential claim amendments in a telephone interview on September 3, 2008. In response to the Final Office Action mailed July 17, 2008 and subsequent to the September 3, 2008 interview, the undersigned submits the following amendment and remarks. Upon entry of the amendment, claims 1, 3-14, 16-25, and 31-37 are pending in the application. The present amendment amends claims 1, 3, 14, 16-25, cancels claims 26 and 28-30, and adds new claims 31-37. Claims 2, 15, and 27 remain cancelled. No new matter has been added by the present amendment.

The present response is believed to overcome all of the prior Office Action rejections, and allowance of the pending claims is kindly requested.

II. Rejection of Claims 1, 3-14, 16-22, 26, and 28-30

The Office Action rejected claims 1, 3-14, 16-22, 26, and 28-30 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a second component, does not reasonably provide enablement for a first component. The present response cancels claims 26 and 28-30, so the rejection of these claims is moot.

Moreover, the § 112 enablement rejection is also moot as to claims 1, 3-14, and 16-22, as the “first component” mentioned by the Examiner is not claimed anywhere in any of these pending claims. Rather, all of the pending claims recite a “prosthetic component.” The

recitation of a “prosthetic component” is enabled for at least the following reasons: (1) the drawings illustrate an acetabular cup (11); (2) the abstract and paragraphs [0001], [0026], and [0032] of the specification, as well as others, state that the component may take the form of a prosthetic or an acetabular cup.

Thus, the undersigned respectfully requests that the § 112 rejection be withdrawn.

Additionally, the Office Action states that “[t]he second component is solely discloses (sic) as a patient’s bone which is not a component since it is non-statutory subject matter which can not be considered as a component of the invention.” July 17, 2008 Final Office Action, p. 3. Although it is not clear whether any claims are rejected in light of this statement, the undersigned respectfully submits that none of the pending claims recite a “second component,” and thus any rejection relating to this recitation is moot.

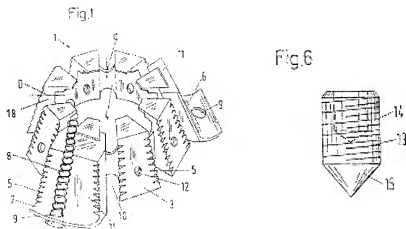
III. Rejection of Claims 1-7, 14, 17, 19-22 and 28-30 Under 35 U.S.C. § 102

The Office Action rejected claims 1-7, 14, 17, 19-22 and 28-30 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,549,692 to *Hauser et al.* (“*Hauser*”). Claim 2 was previously cancelled and the present response cancels claims 28-30, so rejection of these claims is moot.

A. Hauser

As shown in Figure 1 below, *Hauser* discloses a hipjoint shell 1 that is anchored in the pelvis. Supporting bodies 11 are fixed to regions 3 with setscrews 13 (shown in Figure 6 below), which are screwed from inside the shell 1 to connect the supporting bodies 11 to the regions 3 of the shell 1. *Hauser*, col. 2, ll. 64-67. As shown below, setscrew 13 does not

pass through an aperture extending through the supporting body 11. Thus, setscrew 13 does not secure purchase to a bone, much less secure a fixing member to a prosthetic component independent of whether the screw gains purchase in the bone.



The supporting body 11 covers the entire region 3 of the shell 1 to enlarge the shell 1. *Hauser*, col. 1, ll. 20-32. Because supporting body 11 is attached to the region 3 of the shell 1 with a setscrew 13, the supporting body 11 is not rotatably adjustable relative to the shell 1. *Hauser*, col. 1, ll. 64-67; col. 2, ll. 64-67. A second bone screw 8 can then be inserted through a drilled hole 9 provided in the support body 11. Notably, however, the bone screw 8 does not fix the supporting body 11 to the shell 1. *Hauser*, Fig. 1, col. 3, ll. 19-21.

B. *Hauser Does Not Anticipate Pending Claims 1, 3-7, 14, 17, or 19-22.*

For a reference to anticipate a claim under § 102, it must describe, either expressly or inherently, each and every element set forth in the claim. MPEP § 2131. *Hauser* does not describe, either expressly or inherently, each and every element set forth in the pending claims.

Amended claim 1 requires a fixing assembly having a prosthetic component, a fixing member, and a screw that passes through an aperture extending through the fixing member to secure the fixing member to the prosthetic component. Moreover, pending claim 1 requires that the screw be oriented in the aperture of the fixing member to secure purchase of the screw to a bone in which the prosthetic component is implanted, so that disposition of the screw in the fixing member causes securing of the fixing member to the prosthetic component to occur whether or not the screw gains purchase in the bone.

Similarly, new claim 35 requires a fixing assembly having an acetabular cup, a fixing member, and a screw that is threadably received in an aperture extending through the fixing member to secure the fixing member to the acetabular cup. Moreover, pending claim 35 requires that the screw be oriented in the aperture of the fixing member to secure purchase of the screw to a bone in which the acetabular cup is implanted, so that disposition of the screw in the fixing member causes securing of the fixing member to the acetabular cup to occur whether or not the screw gains purchase in the bone.

New claim 31 provides a method for securing a fixing member to an acetabular cup including securing the fixing member to the acetabular cup by inserting a screw through an aperture extending through the fixing member, whereby the screw passes through the aperture, and orienting the screw in the aperture of the fixing member to secure purchase of the screw to a bone in which the acetabular cup is implanted, wherein disposition of the screw in the fixing member causes securing of the fixing member to the acetabular cup to occur whether or not the screw gains purchase in the bone.

Figure 2 below shows one non-limiting embodiment of a fixing assembly including an acetabular cup 11, a fixing member 12, and a screw 13. In this embodiment, the screw 13 passes through an aperture extending through the fixing member to secure the fixing member to the prosthetic component. The screw is oriented in the aperture of the fixing member to secure purchase of the screw to a bone in which the acetabular cup is implanted, so that disposition of the screw in the fixing member causes securing of the fixing member to the acetabular cup to occur whether or not the screw gains purchase in the bone.

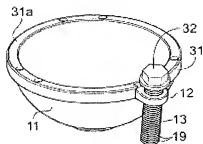


Fig. 2

Hauser does not describe expressly or inherently a fixing assembly having a fixing member and a screw that passes through an aperture extending through the fixing member to secure the fixing member to the prosthetic component. As explained above, claims 1, 31 and 35 require that a screw pass through an aperture extending through the fixing member to secure the fixing member to the prosthetic component. Moreover, claims 1, 31, and 35 require that the screw be oriented in the aperture of the fixing member to secure purchase of the screw to a bone in which the prosthetic component is implanted, so that disposition of the screw in the fixing member causes securing of the fixing member to the prosthetic component to occur whether or not the screw gains purchase in the bone.

The Office Action construes the regions 3 of the shell 1 as a component and the supporting body 11 as a fixing member. *Hauser* discloses the use of a setscrew 13 to secure a supporting body 11 onto the shell 1. *See* Fig. 1, col. 2, ll. 55-59 and 64-67. However, the setscrew 13 does not pass through an aperture that extends through supporting body 11, as required by amended claims 1, 31, and 35. Accordingly, *Hauser* does not disclose a screw that passes through an aperture extending through the fixing member to secure the fixing member to the prosthetic component. Thus, independent claims 1, 31, and 35 are not anticipated by *Hauser*.

In fact, *Hauser* teaches away from fixing assemblies that include a screw that passes through an aperture extending through the fixing member to secure the fixing member to a prosthetic component because *Hauser* discloses securing a supporting body to a shell using a screw that does not pass through an aperture extending through the supporting body. Thus, this screw cannot secure purchase to a bone.

Moreover, *Hauser* does not disclose the orientation of setscrew 13 in an aperture of a supporting body 11 to secure purchase of the screw to a bone in which the shell 1 is implanted, so that disposition of the setscrew in the supporting body 11 causes securing of the supporting body 11 to the shell 1 to occur whether or not the setscrew 13 gains purchase in the bone, as required by claims 1, 31, and 35. As explained above, the setscrew 13 of *Hauser* does not pass through an aperture extending through the supporting body 11. Therefore, setscrew 13 cannot gain purchase on a bone at all, much less secure a fixing member to a prosthetic component independent of whether it gains purchase on the bone, as

required by claims 1, 31, and 35. For this additional reason, *Hauser* does not anticipate independent claims 1, 31, and 35.

Claims 3-14, 16-22, and 32-34 depend from claim 1, and thus dependent claims 3-14, 16-22, and 32-34 are patentable for the same reasons independent claim 1 is patentable, and may be patentable for additional reasons. Claims 36-37 depend from claim 35, and thus dependent claims 36-37 are patentable for the same reasons independent claim 35 is patentable, and may be patentable for additional reasons.

Accordingly, the undersigned submits that claims 1, 3-14, 16-22, and 31-37 are not anticipated by *Hauser* and are in a condition for allowance.

IV. Rejection of Claims 23-26 Under 35 U.S.C. § 102

The Office Action rejected claims 23-26 under 35 U.S.C. § 102(b) as being anticipated by *Hauser*. For a reference to anticipate a claim under § 102, it must describe, either expressly or inherently, each and every element set forth in the claim. MPEP § 2131. *Hauser* does not describe, either expressly or inherently, each and every element set forth in claims 23-26. The present response cancels claim 26, so the rejection of claim 26 is moot.

Amended claim 23 requires a kit of parts for a fixing assembly having at least one prosthetic component, a fixing member, and a screw that passes through an aperture in the fixing member to translationally secure the fixing member to the at least one prosthetic component, where the fixing member and the prosthetic component are rotatably adjustable relative to one another. Moreover, amended claim 23 requires that the screw be oriented in the aperture of the fixing member to secure purchase of the screw to a bone in which at least

one prosthetic component is implanted, so that disposition of the screw in the fixing member causes securing of the fixing member to at least one prosthetic component to occur whether or not the screw gains purchase in the bone.

Hauser only discloses attaching a supporting body 11 to a shell 1 at a fixed position. *Hauser*, col. 1, ll. 64-67; col. 2, ll. 64-67. In fact, *Hauser* explicitly discloses “fixing the supporting body an (sic) exact position of it relative to the shell . . .” *Hauser*, col. 1, ll. 65-67. In other words, *Hauser* teaches that the supporting body and the shell are not rotatably adjustable relative to one another. Accordingly, *Hauser* does not expressly or inherently disclose a screw that passes through an aperture in the fixing member to translationally secure the fixing member to at least one prosthetic component, where the fixing member and the prosthetic component are rotatably adjustable relative to one another, as required by amended claim 23.

Moreover, *Hauser* does not disclose the orientation of setscrew 13 in an aperture of a supporting body 11 to secure purchase of the screw to a bone in which the shell 1 is implanted, so that disposition of the setscrew in the supporting body 11 causes securing of the supporting body 11 to the shell 1 to occur whether or not the setscrew 13 gains purchase in the bone, as required by claim 23. As explained above, the setscrew 13 of *Hauser* does not pass through an aperture extending through the supporting body 11, as required by claim 23. Therefore, setscrew 13 cannot gain purchase on a bone at all, much less secure a fixing member to a prosthetic component independent of whether it gains purchase on the bone, as

required by claim 23. For this additional reason, *Hauser* does not anticipate independent claim 23.

Claims 24-25 depend from claim 23, and thus dependent claims 24-25 are patentable for the same reasons independent claim 23 is patentable, and may be patentable for additional reasons.

Accordingly, the undersigned submits that claims 23-25 are not anticipated by *Hauser* and are in a condition for allowance.

V. 35 U.S.C. § 103 Rejections

The Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex*, Federal Register, Vol. 72, No. 195, p. 57527 (October 10, 2007) explain what is required where an obviousness rejection is made:

As reiterated by the Supreme Court in *KSR*, the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in *Graham v. John Deer Co.* Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

- (1) Determining the scope and content of the prior art;
 - (2) Ascertaining the difference between the claimed invention and the prior art; and
 - (3) Resolving the level of ordinary skill in the pertinent art.
- Objective evidence relevant to the issue of obviousness must be evaluated by Office personnel. . . .

Office personnel fulfill the critical role of fact finder when resolving the *Graham* inquiries. . . . Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. . . .

Once the findings of fact are articulated, Office personnel must provide an explanation to support an obviousness rejection under 35 U.S.C 103.

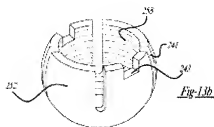
The undersigned respectfully submits that the July 17, 2008 Office Action does not fulfill these requirements. For the reasons explained in detail below and with specific reference to the Examiner's rejections, none of *Hauser*, U.S. Patent No. 6,475,241 to *Pappas* ("*Pappas*"), U.S. Patent No. 6,416,553 to *White* et al. ("*White*"), U.S. Patent No. 6,162,257 to *Gustilo, et al.* ("*Gustilo*"), or any other relevant prior art of record, either alone or in combination, discloses each and every element of the amended claims.

A. *Rejection of Claims 8-12 and 16*

The Office Action rejected claims 8-12 and 16 under 35 U.S.C. § 103(a) as being unpatentable over *Hauser* in further view of *White*. Neither *Hauser* nor *White* teaches, discloses, or suggests each and every element of pending claims 8-12 and 16. Accordingly, the undersigned respectfully traverses this rejection and requests that it be withdrawn.

As explained above, *Hauser* does not disclose each and every element of pending claim 1. Claims 8-12, and 16 depend from claim 1, and therefore *Hauser* does not disclose each and every element of pending claims 8-12 and 16, for at least the reasons stated above.

Moreover, *White* discloses an acetabular prosthesis that includes an acetabular cup and a modular attachment component, the component including an attachment member and an engagement member. Claim 8 requires that the male location feature have a slit, such that the male location feature is divided into two arms. The Action states that *White* teaches a fixing member with a male feature that has slots 241 and notches 243, as shown in Figure 13b reproduced below.



The undersigned respectfully disagrees that Figure 13b discloses a male location feature with a slit that divides the male location feature into two arms, as required by claim 8. Specifically, if the male location member is located on the fixing member, the male location feature of claim 8 must fit together with a female location feature located on the prosthetic component. *White* does not disclose, teach, or suggest a male location feature on a fixing member that fits together in use with a female location on a prosthetic component. And *White* certainly does not disclose, teach, or suggest a male location feature having a slit that divides a male location feature into two arms that fits together with a female location feature on a prosthetic component. Claim 9 depends from claim 8, and claims 10 and 16 depend from claim 9, and therefore none are made obvious by either *Hauser* or *White* for at least the reasons above, and may be nonobvious for additional reasons. Similarly, claim 11 depends from claim 10, and is therefore not made obvious by either *Hauser* or *White* for at least the reasons above, and may be nonobvious for additional reasons.

The undersigned respectfully disagrees that *Hauser* teaches a screw having a thickened portion to push apart two arms of a male location feature when the screw is

screwed into the aperture of the fixing member, as required by claim 16. Thus, the undersigned traverses the rejection of claim 16 and requests that it be withdrawn.

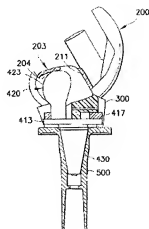
Because neither *Hauser* nor *White* teaches, suggests, or discloses a male location feature on a fixing member having a slit such that the male location feature is divided into two arms, where the male location feature fits together with a female location feature on a prosthetic component, the undersigned respectfully submits that claims 8-12 and 16 are not made obvious by *Hauser* in view of *White*, and respectfully requests withdrawal of the § 103 rejection and allowance of pending claims 8-12 and 16.

B. *Rejection of Claim 13*

The Office Action rejected claim 13 under 35 U.S.C. § 103(a) as being unpatentable over *Hauser* in further view of *Pappas*. Neither *Hauser* nor *Pappas* teaches, suggests, or discloses each and every element of pending claim 13. The undersigned respectfully traverses this rejection and requests that it be withdrawn.

As explained above, *Hauser* does not disclose each and every element of pending claim 1. Pending claim 13 depends from claim 1, and therefore *Hauser* does not disclose each and every element of pending claim 13, for at least the reasons stated above.

Moreover, *Pappas* discloses a knee joint prosthesis including femoral and tibial components. The Action states that *Pappas* teaches a male location feature made of a resiliently deformable material. The undersigned respectfully disagrees with the Office's characterization of feature 430 (shown in the figure reproduced below) as a male location feature that works with a female location feature in the manner required by claim 13.



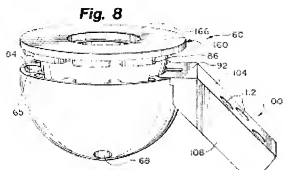
Therefore, in addition to the reasons stated above, neither *Hauser* nor *Pappas* teaches, suggests, or discloses each and every limitation of claim 13, and the undersigned respectfully requests withdrawal of the § 103 rejection and allowance of pending claim 13.

C. *Rejection of Claim 18*

The Office Action rejected claim 18 under 35 U.S.C. § 103(a) as being unpatentable over *Hauser* in further view of *Gustilo*. Neither *Hauser* nor *Gustilo* teaches, suggests, or discloses each and every element of pending claim 18. The undersigned respectfully traverses this rejection and requests that it be withdrawn.

As explained above, *Hauser* does not disclose each and every element of pending claim 1. Pending claim 18 depends from claim 1, and therefore *Hauser* does not disclose each and every element of pending claim 18, for at least the reasons stated above. In addition to the reasons that pending claim 1 is allowable, pending claim 18 is allowable because neither *Hauser* nor *Gustilo* discloses, teaches, or suggests a prosthetic component having a circumferential groove forming a female location feature that locks the fixing

member to the component. The undersigned respectfully disagrees with the Action's characterization that the acetabular cup of Figure 8 (reproduced below) has a circumferential groove as required by claim 18.

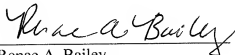


Regardless, *Gustilo* fails to disclose that the circumferential groove forms a female location feature that fits together with a male location feature of a fixing member to lock the fixing member to a prosthetic component, as required by pending claim 18. Therefore, the undersigned respectfully submits that pending claim 18 is not made obvious by *Hauser* in view of *Gustilo*, and respectfully requests withdrawal of the § 103 rejection and allowance of pending claim 18.

CONCLUSION

The undersigned respectfully submits that all pending claims are in a condition for allowance. Any fees due at this time may be charged to Deposit Account number 11-0855. If there are any matters that can be addressed by telephone, the Examiner is urged to contact the undersigned attorney at 404.532.6947.

Respectfully submitted,



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Date: *October 17, 2008*

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